

Response in 10/659,245 to Office Action Mailed July 23, 2004

Amendments to the Claims

1. (Currently Amended) A needle for delivery of a substance to the skin of a patient, having a skin engaging surface, comprising:
a shaft having a wall defining a longitudinally extending bore, a first end that is open to receive a the substance in the bore, a second end adapted to penetrate skin of a subject, and a penetration length extending from the skin engaging surface to a distal tip of the second end of less than about 4.5 mm; and
at least one side port extending through the wall and communicating with the bore, the side port being arranged about 0.025 mm to about 3 mm from the skin engaging surface, wherein when the needle is fully penetrated into the skin, the skin engaging surface contacts the skin, and the substance exits the side port directly into the skin.
2. (Original) The needle of claim 1, wherein the second end comprises a sharpened tip.
3. (Original) The needle of claim 2, wherein the tip is beveled.
4. (Original) The needle of claim 3, wherein the side port is arranged on a side of the shaft opposite of the bevel.
5. (Original) The needle of claim 1, wherein the second end includes an end port communicating with the bore.
6. (Original) The needle of claim 5, wherein the side port and end port are adapted for bi-phasic delivery of a substance.

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7. (Original) The needle of claim 1, wherein the side port is arranged on the shaft for epidermal delivery of a substance.
8. (Original) The needle of claim 1, wherein the side port is arranged on the shaft for intradermal delivery of a substance.
9. (Currently Amended) The needle of claim 1, wherein the side port is adapted to be about ~~.025 mm~~ 0.5 mm to about ~~3 mm~~ 1.5 mm below a surface of the skin when the needle is inserted into a subject.
10. (Withdrawn) An infusion apparatus, comprising:
a housing including a reservoir for containing a supply of liquid medication and for delivering the liquid medication under pressure;
a delivery cannula carried by and extending from the housing, the delivery cannula including a side port communicating with an interior of the cannula, the side port being arranged about .025 mm to about 3 mm below a surface of the skin when the needle is inserted into the skin of a subject;
and a flow channel for conducting the liquid medication from the reservoir to the delivery cannula.
11. (Withdrawn) The apparatus of claim 10, wherein the delivery cannula further comprises a beveled tip.
12. (Withdrawn) The apparatus of claim 11, wherein the beveled tip includes an end port communicating with the interior of the cannula.
13. (Withdrawn) The apparatus of claim 12, wherein the side port is arranged on a side of the cannula opposite the beveled tip.

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14. (Withdrawn) The apparatus of claim 10, further comprising at least two side ports
15. (Withdrawn) The apparatus of claim 10, wherein the side port is arranged on the delivery cannula about 200 microns from the housing.
16. (Withdrawn) The apparatus of claim 10, wherein the side port is arranged on the delivery cannula about .025 to about 1.5 mm from the housing.
17. (Withdrawn) The apparatus of claim 10, wherein the delivery cannula is adapted to penetrate only an intradermal layer.
18. (Withdrawn) A method of delivering a substance to a skin of a subject, comprising:
providing a needle comprising a shaft defining a longitudinally extending bore and having a first end that is open to receive a substance in the bore, a second end adapted to penetrate skin of a subject and at least one side port extending through the shaft and in communication with the bore;
penetrating the skin of a subject with the needle such that at least one side port is arranged about .025 mm to about 3 mm below a surface of the skin;
introducing a substance into the first end of the bore; and
delivering the substance from the bore such that the substance flows out of the side port and into an area of the skin contiguous with the side port.
19. (Withdrawn) The method of claim 18, further comprising delivering the substance via the side port to the epidermis.

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20. (Withdrawn) The method of claim 18, further comprising delivering the substance via the side port intradermally.
21. (Withdrawn) The method of claim 18, wherein the needle has an end port at the second end and further comprising delivering the substance through both the side port and the end port simultaneously.
22. (Withdrawn) The method of claim 18, wherein the needle has an end port at the second end and further comprising performing bi-phasic delivery of the substance.
23. (Withdrawn) The method of claim 18, wherein the at least one side port is arranged about .025 mm to about 1.5 mm below a surface of the skin.
24. (Withdrawn) The method of claim 21, further comprising at least two side ports and performing triphasic delivery of the substance.
25. (Withdrawn) The method of claim 18, providing at least one of a vaccine antigen, DNA and a polysaccharide polymer vaccine as the substance.
26. (Withdrawn) The method of claim 18, further comprising delivering the substance at a steady state delivery pressure less than about 5 psi.
27. (Withdrawn) The method of claim 18, wherein the needle includes an end port and delivering the substance simultaneously through the side port for absorption into a first layer of the skin and through the end

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port for absorption into second layer of the skin that is different from the first layer.

28. (Withdrawn) The method of claim 27, wherein the first layer of the skin is an epidermal layer.

29. (Withdrawn) The method of claim 28, wherein the second layer of skin is an intradermal layer.

30. (Withdrawn) A method for delivering a substance to the skin, comprising:
providing a needle comprising a shaft defining a longitudinally extending bore and having a first end that is open to receive a substance in the bore, a second end adapted to penetrate skin of a subject, and at least one side port extending through the shaft and in communication with the bore;
inserting the needle into the skin of a subject;
introducing a substance into the bore via the first end; and
selectively delivering the substance via the at least one side port into the dermis to obtain absorption of the substance in the dermis.

31. (Withdrawn) The method of claim 30, providing at least one of a vaccine antigen, DNA and a polysaccharide polymer vaccine as the substance.

32. (Withdrawn) The method of claim 30, further comprising delivering the substance at a substantially constant delivery pressure.

33. (Withdrawn) The method of claim 30, further comprising inserting the needle so that at least one side port is arranged about .025 mm to about 3 mm below a surface of the skin.

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34. (Withdrawn) The method of claim 30, wherein the needle includes an end port and further comprising delivering the substance simultaneously through the side port for absorption, wherein a volume of the substance delivered is increased relative to a volume delivered via only an end port.
35. (Withdrawn) The method of claim 30, wherein the needle includes an end port and selectively delivering the substance via the side port and end port to at least one of the epidermal and intradermal space; the intradermal and subcutaneous space; and the epidermal, the intradermal and subcutaneous space.
36. (Withdrawn) The method of claim 30, further comprising delivering the substance at a steady state delivery pressure less than about 5 psi.
37. (Withdrawn) A method of delivering a substance to a selected layer of the skin, comprising:
providing a delivery cannula having a side port and an end port communicating with an interior of the cannula;
inserting the needle into the skin; and
delivering the substance to the selected layer of skin via the side port and the end port wherein a volume of the substance delivered is increased relative to a volume delivered via only an end port.
38. (Withdrawn) The method of claim 37, further comprising inserting the needle into the skin until the side port is about .025 mm to about 3 mm below a surface of the skin.

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39. (Withdrawn) The method of claim 37, wherein the side port is arranged on the needle to be .025 mm to about 3 mm below a surface of the skin when the needle is inserted into the skin.
40. (New) A drug delivery device for intradermal delivery of a substance into skin comprising:
a reservoir containing a selected amount of the substance;
a needle, having a selected gauge size, a distal end, a proximal end and an axis extending from the distal end to the proximal end, wherein the needle defines a lumen which is in fluid communication with the reservoir, the needle further comprising a tip at the distal end, and the lumen further defining at least one outlet substantially at the distal end at a fixed location with respect to the tip, wherein the outlet is formed by an opening through the side of the needle and has an exposed height in the axial direction that is of a selected length less than the thickness of the intradermal space;
means for limiting penetration of the needle into the skin such that when the needle is inserted into the skin to the depth determined by the penetration limiting means, and the outlet is at a location entirely within the intradermal space; and
wherein the gauge size is selected to allow the skin to seal around the needle when in use and leakage of the substance to the surface of the skin is substantially prevented.
41. (New) The needle of Claim 40 wherein the outlet is at a depth of about 0.50 mm to 2 mm when the needle is inserted into the skin.
42. (New) The needle of Claim 41 wherein the outlet is at a depth of about 0.50 mm to 1.5 mm when the needle is inserted into the skin,

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- 43. (New) The needle of Claim 42 which is about 0.30 mm to 2 mm long.
- 44. (New) The needle of Claim 43 which is about 0.50 mm to 1 mm long.
- 45. (New) A device for intradermal delivery of a substance into the skin comprising the needle of Claim 40 and a reservoir in fluid communication with the needle.
- 46. (New) A device as claimed in Claim 45 further optionally comprising pressure-generating means for delivering the substance through the needle.
- 47. (New) A device as claimed in Claim 46 wherein the pressure-generating means provides variable control of substance delivery rate.
- 48. (New) A needle as claimed in claim 40, wherein the penetration limiting means comprises a hub associated with the shaft of the needle.
- 49. (New) A needle as claimed in claim 40, wherein the outlet is a plurality of outlets.